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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,112	05/06/2004	Jaime Simon	61350C	8566

109 7590 09/11/2008

The Dow Chemical Company
Intellectual Property Section
P.O. Box 1967
Midland, MI 48641-1967

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/840,112	SIMON ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RCE Acknowledged

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/19/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Imondi et al (US 4,143,130).

Imondi discloses a method for the treatment of kidney diseases comprising administering swellable polymers to a patient in enterically coated oral formulations and compositions comprising said polymers and are capable of absorbing physiological saline, the patent teaches that the polymers of the invention have a swelling index of 10-1500 (see col. 3 lines 42-47). The carboxylic acid polymers include acrylic acid monomers (see col. 2 lines 10-60). With respect to the enteric coating claimed in claims 3 and 13 of the application, the patent contemplates enterically coated dosage forms,

and the polymers claimed by Applicant are routinely used in the art for enteric coated formulations.

4. Claims 1-2, 4-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Motoki Yonekawa et al (JP H10-130154)

Yonekawa discloses a method of oral administration of drug comprising acrylic type water absorbent monomer as an active component. And acrylic water absorbent resins, said polymer is capable of absorbing ability (volume, mL) of a physiological saline solution absorbed per (1g) is 5 to 100 times of its weight (see para 0026). And acrylic acid type polymers include, acrylic acid metal salt type polymers, methacrylic acid type polymers and polymers that can graft polymerize with acrylic acid are for e.g., the hydrophilic poly saccharides such as starch, carrageenan, agarose, caboxy methyl cellulose and the like (see para 0021). And for ordinary oral administering agents, a general support material can be used to make it into an appropriate shape such as tablets, granules, capsules, and the like (see para 0027). Recitation of directly administering to the intestinal tract of the host reads on oral administration of the prior art, since drug comprising acrylic type water absorbent polymers were uniformly mixed and it was filled in an oral administering hard gelatin capsule of the desired size, so that the polymer is not directly exposed to the stomach prior to delivery to the GI tract.

Response to Argument

Upon further consideration of generic claim 1, and a search of prior art necessitated to the reintroduction of previous art as stated above.

Applicant arguments filed on 05/11/2007 have been fully considered but they are not persuasive.

Applicant asserts that Yonekawa fails to disclose directly administering an effective amount of water-absorbent polymer to the intestinal tract of a host. This argument is not persuasive since Yonekawas discloses the administration of drug comprising acrylic water-absorbent polymer, filled into an oral administering hard gelatin capsule of desired size which will not be absorbed into the internal body, practically, so that its safety is secured.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1, 4-6, 9, 13 and 15-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berger et al (US 4,470,975).

Berger discloses a method of treating edema, comprising orally administering to host an effective amount of a water-insoluble hydrophilic, cross-linked polysaccharide which is capable of absorbing water in the lumen of the gastrointestinal tract and discharging the thus bound water by passage from the alimentary canal in the normal way (see claim 1 and abstract). In another embodiment, the insoluble hydrophilic, cross-linked polysaccharides are capable of absorbing water with swelling, the water regain of

the product being within the range of about 1 to 50 grams per gram of the dry gel product administered (see col. 4 lines, 34-59). And in another embodiment (Fig, 1) illustrates that the water content of feces of rats treated with insoluble hydrophilic, cross-linked dextrans is significantly higher than that of untreated rats. And in another embodiment, discloses experiments showing that diets containing insoluble, hydrophilic, cross-linked carbohydrates are able to divert water elimination from the renal route to the gastrointestinal rout, and remover water from the body by the gastrointestinal route. These pharmalogical properties are of significant therapeutic value in the treatment of edema, water intoxication in chronic renal failure, and in the treatment of other forms of fluid retention such as congestive heart failure, cirrhosis of the liver and other disorders associated with refractor swelling. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a method for increasing fluid loss through the feces in a host comprising the step of directly administering to the intestinal tract of the host an effective amount of a water-absorbent polymer for increasing the fluid in the feces, a theological modified, a water-absorbent polymer because both Applicant and Berger et al discloses method for increasing fluid loss through the feces in a host comprising such components.

7. Claims 1-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Motoki Yonekawa et al (JP H10-130154) or Imondi et al (US 4,143,130) in view of Berger et al (US 4,470,975).

The teaching of Imondi and Yonekawa et al is stated as above.

Imondi and Yonekawa et al does not teach the enteric coating polymer selected from at least one of hydroxypropylmethylcellulose, hydroxypropylmethylcellulose phthalate, methylacrylic acid polymers or polymers of derivatives of methylacrylic acid therein.

Tsuji discloses of administering an enteric coated hard capsules comprising, drug-filled hard capsules with a film-forming substance which is selectively soluble in the digestive juice, e.g., an enteric coating agent, such as hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose acetate succinate, methacrylic acid-methyl methacrylate copolymer and natural products such as shellac (see abstract and col. 2 lines 35-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combination of cellulosic polymers and the composition in the form of enteric coated tablet or capsule for treatment of excess fluid in the gastrointestinal tract as taught by Imondi and Yonekawa. By coating the tablet or capsule with enteric polymer, they are not disintegrated in the stomach but they are transported to the intestine, where they are disintegrated, followed by absorption of the active ingredient and production of biological or pharmaceutical effects thereof. One of ordinary skill would expect to obtain an intact and therefore effective composition for removing excess fluid from the body---without the enteric coating, the polymer in the composition (methylacrylic acid and polysaccharide) would be more susceptible to degradation by the acidic environment of the stomach (see col. 3 lines 15-25 and col. 4 lines 3-8).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

1. No claims are allowed at this time.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr